

Composition : Dsec-30 : Each Capsule Contains Dexlansoprazole INN 30mg as enteric coated granules.

Dsec-60 : Each Capsule Contains Dexlansoprazole INN 60mg as enteric coated granules. **Description :** Dexlansoprazole delayed-release capsule is a Proton Pump Inhibitor (PPI) that inhibits gastric acid secretion. Dexlansoprazole is the R-enantiomer of lansoprazole (A racemic mixture of the R- and S-enantiomers). Dexlansoprazole is supplied as a Dual Delayed Release (DDR) formulation in a capsule for oral administration. Dexlansoprazole capsule contains a mixture of two types of enteric coated granules with different pH-dependent dissolution profiles.

Indications : Dexlansoprazole is indicated for-

- Healing of Erosive Esophagitis (EE).
- Maintenance of Healed Erosive Esophagitis.
- Symptomatic Non-Erosive Gastroesophageal Reflux Disease (GERD).

Dosage and administration : Dexlansoprazole dosing recommendations

Indication	Recommended Dose	Frequency
Healing of EE	60 mg	Once daily for up to 8 weeks
Maintenance of Healed EE	30 mg	Once daily
Symptomatic Non-Erosive GERD	30 mg	Once daily for 4 weeks

- Dexlansoprazole can be taken with or without food.
- This capsules should be swallowed whole; Should not be chewed.
- Alternatively, capsules can be administered as follows:
 - Open capsule.
 - Sprinkle intact granules on 1 table spoon.
 - Swallow immediately. Granules should not be chewed.

Or, as directed by the registered physicians.

Side effects : Common side effects include headache, nausea, vomiting, diarrhoea, abdominal pain, upper respiratory tract infection and flatulence.

Contraindication : Dexlansoprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.

Use in pregnancy and lactation : Pregnancy Category B. There are no adequate and well-

Dsec Capsule

controlled studies with dexlansoprazole in pregnant women. It is not known whether dexlansoprazole is excreted in human milk.

Precaution : Gastric malignancy, *Clostridium difficile* associated diarrhoea, bone fracture, hypomagnesemia, concomitant use of Dexlansoprazole with Methotrexate.

Drug Interaction : Dexlansoprazole should not be co-administered with Atazanavir, Warfarin, Tacrolimus, Clopidogrel & Methotrexate.

Overdose : There have been no reports of significant overdose of Dexlansoprazole. Multiple doses of Dexlansoprazole 120mg and a single dose of Dexlansoprazole 300mg did not result in any severe adverse events.

Storage : Away from light. Keep all medicines away from children.

Packing : Dsec-30 : Each box contains 30 capsules in alu-alu blister pack.

Dsec-60 : Each box contains 28 capsules in alu-alu blister pack.